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[REDACTED] EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/902,287	MINOGUE ET AL.
	Examiner	Art Unit
	Kristen L Droesch	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 March 2002 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-71 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 10 July 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 . 6) Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Ireland on Jan 11, 1999. It is noted, however, that applicant has not filed a certified copy of the S990016 application as required by 35 U.S.C. 119(b).

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: ABDOMINAL BELT WITH ADJUSTABLE ELECTRODES.

Claim Objections

3. Claim 35 is objected to because of the following informalities: in line 2, "extends" should be changed to --extending--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15-17, 19-20, 27, 33-36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 15 recites the limitation "the rest of the attachment means" in lines 3-4.

Claim 16 recites the limitation "each main locating means" in lines 3-4, while claim 1 refers to "a main locating means".

Claim 19 recites the limitation "the corresponding set of secondary locating means" in lines 2-3.

Claim 20 recites the limitation "the corresponding set of secondary locating means" in line 2.

Claim 27 recites the limitation "each central electrode" in line 1.

Claim 33 recites the limitation "each main contact means" in lines 2-3

Claim 34 recites the limitation "each electrical connecting means" in line 1, while claim 33 refers to "a main electrical connecting means".

Claim 35 recites the limitation "each secondary contact means" in lines 2-3.

Claim 36 recites the limitation "each electrical connecting means" in line 1, while claim 35 refers to "a secondary electrical connecting means".

There is insufficient antecedent basis for these limitations in these claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 8-11, 14-15, 21-26, 30-31, 38-39, 52-55, 59 and 61-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Linder (5,190,036).

Regarding claim 1, Linder shows attachment means (14) for extending around the torso of a subject; a main locating means (triangular reference 26) for locating a central electrode (the central electrode of the three electrodes on the right or the central electrode of the three electrodes on the left) adjacent the umbilicus of the subject; and two secondary locating means (semi-circular references 26 on either side of triangular reference 26) provided on the attachment means disposed on opposite sides of the main locating means for locating two corresponding side electrodes (any of the top or bottom electrodes (18) of the three electrodes on the right or left) spaced apart from the central electrode (18) (Fig. 1).

With respect to claim 2, Linder shows the two corresponding electrodes are spaced apart from the central electrode in a general direction towards a corresponding *one* of the left or right mid axillary line of the torso intermediate the rib cage and the corresponding right and left iliac crests. The examiner points out that the central electrode could be interpreted to be the middle electrode of the three electrodes (18) located on the left side of the belt, and the two corresponding electrodes could be any of the three electrodes (18) located on the right side of the belt in a general direction towards a corresponding right mid axillary line of the torso intermediate the rib cage and the corresponding right iliac crest.

Regarding claims 3-5, Linder shows the secondary locating means (semi-circular references 26 on either side of triangular reference 26) are disposed on the attachment means for locating the respective side electrodes adjacent the corresponding mid-axillary line or adjacent or toward the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest (Fig. 1).

Regarding claims 8-10, Linder shows the a reference means (26) for locating the attachment means on the torso relative an anatomic reference, circumferentially around the torso and vertically along the torso (Fig. 1).

With respect to claim 11, Linder shows the main locating means (triangular reference 26) acts as a reference means for locating the attachment means relative to the umbilicus (Fig. 1).

Regarding claims 14-15, Linder further shows the attachment means is formed of resilient material (Col. 2, lines 66-67).

With respect to claims 21-22, Linder further shows each main and secondary locating means (26) is provided as a visually perceptive locating means and formed as a corresponding locating mark on the attachment means (Fig. 1).

Regarding claims 23-25, Linder shows each locating means is adapted for locating a patch type electrode and the at least three electrodes are formed as a removable part of the device (Fig. 1; Col. 3, lines 24-28).

With respect to claim 26, Linder shows each side electrode is sized to cover at least a portion of the corresponding lower thoracic nerves and corresponding first and second lumbar nerves (Fig. 1).

Regarding claims 30-31, Linder further shows an electrically conductive gel-type coating provided on a side of each electrode facing away from the attachment means for electrically coupling the electrode to the torso of the subject (Col. 3, lines 24-33).

With respect to claims 38-39, Linder further shows the attachment means comprises a belt (14) and a securing means (Fig. 1; Col. 2, line 67-Col. 3, line 3).

Regarding claim 52, Linder shows a method comprising providing at least three electrodes (18), one of the at least three electrode being a central electrode located adjacent the

umbilicus of the subject, and the other two electrodes are side electrodes spaced apart on the subject from the central electrode and located on the subject on respective sides of the central electrode in a general direction towards *one* of the left and right mid axillary lines intermediate the rib cage and corresponding left and right iliac crests and passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes. Again, the examiner points out that the central electrode could be interpreted to be the middle electrode (18) of the three electrodes (18) located on the left side of the belt, and the two corresponding electrodes could be any of the three electrodes (18) located on the right side of the belt in a general direction towards a corresponding right mid axillary line of the torso intermediate the rib cage and the corresponding right iliac crest.

With respect to claims 53-55, Linder shows each side electrode (18) is located towards and adjacent the midpoint of the corresponding mid axillary line of the torso intermediate the rib cage and the corresponding iliac crest (Fig. 1).

Regarding claim 59, Linder further shows the step of applying the at least one pulse signal to the subject.

With respect to claims 61-63, Linder shows a plurality of pulses at intervals in the range of 5 milliseconds to 1000 milliseconds and in the range of 20 milliseconds to 40 milliseconds and approximately 30 milliseconds \pm 20% (Col. 3, lines 51-52). 40Hz roughly corresponds to an interval of 25 milliseconds and 70Hz roughly corresponds to an interval of 14 milliseconds.

Regarding claim 64, Linder shows the interval between pulses is adjustable (Col. 3, lines 38-41, 54-61).

With respect to claims 65-68, Linder shows each pulse signal comprises pulses of duration in the range of 50 microseconds to 2000000 microseconds, pulses of duration in the

range of 50 microseconds to 1000 microseconds, pulses of duration in the range of 100 microseconds to 500 microseconds, pulses of duration of approximately 300 microseconds ± 20% (Col. 3, lines 46-50).

Regarding claim 69, Linder shows the duration of each pulsed is adjustable (Col. 3, lines 38-41, 46-50).

With respect to claim 70, Linder shows each pulsed signal comprises a plurality of pulses of magnitude in the range of 0mA to 100mA (Col. 3, lines 65-68).

Regarding claim 71, Linder shows the magnitude of each pulse of each pulsed signal is adjustable (Col. 3, lines 38-41, 62-68).

9. Claims 1-12, 14-23, 27-28, 32-36, 38-39, 52-60, and 71 are rejected under 35 U.S.C. 102(e) as being anticipated by Hurtado (6,341,237).

Regarding claim 1, Hurtado shows a device including attachment means (120) for extending around the torso of a subject; a main locating means (track 36) for locating a central electrode (144) adjacent the umbilicus of the subject; and two secondary locating means (tracks 36) provided on the attachment means disposed on opposite sides of the main locating means for locating two corresponding side electrodes (146, 148, 150, 152) of the at least three electrodes spaced apart from the central electrode (144) (Fig 9; Col. 10, line 40-Col. 11, line 17; Figs. 3 6; Col 9, lines 51-58).

With respect to claim 2, Hurtado shows the two corresponding electrodes (146, 148, 150, 152) are spaced apart from the central electrode (144) in a general direction towards a corresponding one of the left or right mid axillary line of the torso intermediate the rib cage and the corresponding right and left iliac crests (Fig 9; Col. 10, line 40-Col. 11, line 17).

Regarding claims 3-5, Hurtado shows the secondary locating means (tracks 36) are disposed on the attachment means for locating the respective side electrodes toward the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest, adjacent the corresponding mid-axillary line, and adjacent the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest (Fig 9; Col. 10, line 40-Col. 11, line 17; Figs. 3 6; Col 9, lines 51-58).

With respect to claims 6-7, Hurtado shows the main locating means (track 36) is disposed on the attachment means for locating the central electrode on the umbilicus and extending completely around the umbilicus (Figs. 7-9, Col. 4, line 65-Col. 5, line 21; Col. 10, lines 53-60).

Regarding claims 8-10, Hurtado shows the a reference means (tracks 36) for locating the attachment means on the torso relative an anatomic reference, circumferentially around the torso and vertically along the torso (Figs. 3, 6-9).

With respect to claim 11, Hurtado shows the main locating means (track 36 for electrode 144) acts as a reference means for locating the attachment means relative to the umbilicus (Figs. 3, 6-9; Col. 4, line 65-Col. 5, line 21; Col. 10, lines 53-60).

Regarding claim 12, Hurtado shows at least two sets (tracks 36 of electrodes 150 and 152, and tracks 36 for electrodes 146, and 148) of at least two secondary locating means disposed on the opposite sides of the main locating means (Figs. 3, 6, 9).

With respect to claims 14-15, Hurtado further shows the attachment means is formed of resilient material (Col. 10, line 45-47;Col. 9, lines 3-20).

Regarding claims 16-18, Hurtado further shows the main electrically conductive contact means (36) is provided on the attachment means corresponding to the main locating means and located within and adjacent to the main locating means (36) (Col. 9, lines 54-55).

Regarding claims 19-20, Hurtado further shows each secondary contact means (tracks 36) is located adjacent the secondary locating means or the corresponding set of secondary locating means (Figs. 3, 6, 9).

With respect to claims 21-22, Hurtado further shows each main and secondary locating means (tracks 36) is provided as a visually perceptive locating means and formed as a corresponding locating mark on the attachment means (Figs. 3, 6).

Regarding claim 23, Hurtado shows each locating means (36 is adapted for locating a patch type electrode (Figs. 2, 3, 6).

With respect to claim 27, Hurtado shows each central electrode (140, 142, 144) is sized to extend substantially across the rectus abdominus muscle (Fig. 9; Col. 10, line 40-Col. 11, line 17).

Regarding claim 28, Hurtado further shows the area of contact of each side electrode (146, 148, 150, 152) does not exceed the area of contact of the central electrode (144) (Fig. 9).

With respect to claim 32, Hurtado further shows a receiving means provided in the attachment means for receiving a signal generating means (121) (Col. 11, lines 19-20).

Regarding claims 33-36, Hurtado further shows main and secondary electrical connecting means (dashed lines) extending between the receiving means and the signal generating means (121) and the main contact means (Figs. 1-3, 6, 9).

With respect to claim 38-39, Hurtado further shows the attachment means comprises a belt (124) and a securing means (130) (Fig. 9).

Regarding claim 52, Hurtado shows a method comprising providing at least three electrodes (140, 142, 144, 146, 148, 150, 152), one of the at least three electrodes being a central electrode (140, 142, 144) located adjacent the umbilicus of the subject, and the other two

electrodes are side electrodes spaced apart on the subject from the central electrode and located on the subject on respective sides of the central electrode in a general direction towards one of the left and right mid axillary lines intermediate the rib cage and corresponding left and right iliac crests and passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes (Fig. 9; Col. 4, line 48-Col.5, line 21; Col. 10, line 40-Col. 11, line 33).

With respect to claims 53-55, Hurtado shows each side electrode (146, 148, 150, 152) is located towards and adjacent the midpoint of the corresponding mid axillary line of the torso intermediate the rib cage and the corresponding iliac crest (Fig 9; Col. 10, line 40-Col. 11, line 17).

With respect to claims 56-57, Hurtado shows the central electrode (140, 142, 144) is located on the umbilicus and extends completely around the umbilicus (Figs. 7-9, Col. 4, line 65-Col. 5, line 21; Col. 10, lines 53-60).

Regarding claim 58, Hurtado shows the central electrode (140, 142, 144) is located on the umbilicus but with a greater area of the central electrode (142, 144) located below the umbilicus than above the umbilicus (144, 140) (Fig. 9; Col. 10, line 40-Col. 11, line 33).

With respect to claim 59, Hurtado further shows the step of applying the at least one pulse signal to the subject.

Regarding claim 60, Hurtado further shows the at least one pulsed signal is applied simultaneously to each of the side electrodes (Col. 11, lines 27-33).

Regarding claim 71, Hurtado further shows the magnitude of each pulse of each pulsed signal is adjustable (Col. 3, lines 63-67).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) as applied to claim 12. Hurtado discloses the claimed invention except for each set of secondary locating means comprising three secondary locating means. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify each set of secondary locating means with two secondary locating means as taught by Hurtado with each set of secondary locating means having three secondary locating means, since applicant has not disclosed that this third locating means provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any number of secondary locating means in the set of secondary locating means such as the two secondary locating means as taught by Hurtado for locating electrodes on the belt.

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linder (5,190,036). Linder discloses the claimed invention except for the specific size of the each side electrode. It would have been an obvious matter of design choice to form the side electrode having a width of 50 mm to 150 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237). Hurtado discloses the claimed invention except for the specific size of the each side electrode. It would have been an obvious matter of design choice to form the side electrode having a width of 50 mm to 150 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

14. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) as applied to claim 32 above, and further in view of Russek (4,381,012). Although Hurtado fails to show the receiving means is a releasable receiving means for releasably receiving the signal generating means, attention is directed to Russek which shows a similar device and teaches that the attachment means comprises receiving means made of VELCRO for releasably receiving the signal generating means. Russek teaches that the releasable receiving means allows for the signal generating means to be located in a convenient location on the attachment means (Col. 6, lines 43-53). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hurtado with receiving means made of VELCRO for releasably receiving the signal generating means in order to allow for the signal generating means to be located in a convenient location on the attachment means.

15. Claims 40-45, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) as applied to claim 1 above, and further in view of Russek (4,381,012). Although Hurtado fails to show a main fastening means provided corresponding to the main locating means and secondary fastening for fastening the respective side electrodes to the attachment means adjacent the secondary located means, attention is directed to Russek which

shows a similar device with fastening means comprising stud fasteners (Figs. 9-11, 18; Col. 5, lines 26-54). Russek teaches that utilizing stud fastener fastening means is advantageous since it allows wires to be run external to the belt rather than within the belt resulting in a minimal number of wires that can be damaged during laundering (Col. 5, lines 47-54). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hurtado with a main fastening means and secondary fastening means comprising stud fasteners since Russek teaches stud fastener fastening means are advantageous since it allows wires to be run external to the belt rather than within the belt resulting in a minimal number of wires that can be damaged during laundering.

Regarding claim 44, Russek further shows each stud fastener comprises a female (61-66) and male part (66') (Figs. 9-10, 18)

With respect to claim 45, Russek further shows each stud fastener is electrically conductive (Col. 5, lines 26-54).

Regarding claims 48-49, Russek shows each stud fastener comprises a first part (57) for attaching to a corresponding electrode and a second part (66) for attaching to the attachment means wherein the first and second parts engage each other with electrically conductive engagement.

16. Claims 46-47, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurtado (6,341,237) and Russek (4,381,012) as applied to claims 44 and 48 above. Hurtado and Russek disclose the claimed invention except for showing the exposed surface of the portions of each stud fastener attached to the attachment means is of electrically insulating material provided by an electrically insulated coating. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the exposed portions of the

stud fasteners as taught by Hurtado and Russek with insulating coatings in order to protect a user who may come into contact with the exposed portions of the stud fasteners from electrical shock.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drosch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

kld

Kristen Drosch

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